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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/512,581

02/24/2000

Ana M. Soto

MBI-008

5767

30623

7590

10/28/2004

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
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ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/512,581	SOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stephen L. Rawlings, Ph.D.	1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,8-12,47,48 and 68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5,8-12,47,48 and 68 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>20041019</u> .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.  | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> .     |

### **DETAILED ACTION**

1. The amendment filed May 17, 2004 is acknowledged and has been entered. Claims 6, 7, and 49-51 have been canceled. Claims 4, 5, 11, 12, 47, and 48 have been amended. Claims 68 and 69 have been added.
2. The amendment filed August 16, 2004 is acknowledged and has been entered. Claims 3, 13-46, 52-67, and 69 have been canceled. Claims 5, 8, 9, 12, 47, and 48 have been amended.
3. The executed copies of the declaration under 37 CFR § 1.132 by the inventors filed May 17, 2004 and August 16, 2004 is acknowledged and have been entered.
4. Claims 1, 2, 5, 8-12, 47, 48, and 68 are pending in the application.
5. The grounds of rejection and objection set forth in the previous Office action mailed December 17, 2003 have been rendered moot by Applicant's declaration and withdrawn or withdrawn upon favorable consideration of Applicant's arguments in view of the amendments. For clarity of record, it is noted that the prior art does not teach or fairly suggest a nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 3 encoding the amino acid sequence set forth as SEQ ID NO: 2. While the prior art teaches a nucleic acid encoding a protein designated AS3 (e.g., GenBank™ Accession No. U95825), the polynucleotide sequence of the nucleic acid of the prior art differs from the polynucleotide sequences set forth as SEQ ID NO: 1 and SEQ ID NO: 3; the polynucleotide sequence of the prior art is 99.1% identical to SEQ ID NO: 1, having 20 mismatches at positions throughout the aligned sequences. Accounting for these differences, Applicant's representative, Dr. Guterman explained during the interview of August 13, 2004, that the polynucleotide sequence taught by the prior art and the polynucleotide sequence of the claimed nucleic acid represent different clones encoding polypeptides comprising different amino acid sequences, not the same isolated nucleic acid.

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6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gregory Sieczkiewicz, Ph.D. on October 19, 2004.

The application has been amended as follows:

A. The claims have been amended as follows:

5. (Currently Amended) An isolated nucleic acid molecule consisting of a fragment of at least 250 nucleotides of a nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or 3, or a full complement thereof.

68. (Currently Amended) An isolated nucleic acid molecule comprising ~~nucleotides 1-5253~~ of the nucleotide sequence set forth in SEQ ID NO:1.

B. The specification has been amended as follows:

(a) At page 3, line 30, the number "5253" has been deleted and replaced with the number "5271".

(b) At page 9, line 3, the number "5253" has been deleted and replaced with the number "5271".

(c) At page 14, line 7, the number "5253" has been deleted and replaced with the number "5271".

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(d) At page 10, line 11, the number "5337" has been deleted and replaced with the number "5355".

(e) At page 16, line 6, the number "5253" has been deleted and replaced with the number "5271".

7. This application is in condition for allowance except for the following formal matters:

(a) The drawing labeled as Fig. 6-2 incorrectly indicates the length of the depicted polynucleotide sequence to be 5337 nucleotides, since the polynucleotide sequence is the polynucleotide sequence set forth SEQ ID NO: 4, which is 5355 nucleotides. Replacement of the drawing with appropriate correction is required.

(b) The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Sequences appearing in the specification and/or drawings must be identified by sequence identifier in accordance with 37 C.F.R. 1.821(d). According to 37 CFR § 1.821(a), an unbranched sequence of four or more specifically identified amino acids or an unbranched sequence of ten or more nucleotides must be identified by sequence identification numbers. See MPEP § 2422.01.

In this instance, the sequences depicted in Figures 2, 3, and 5 are not identified by sequence identification numbers, either in the figure or in the brief description of figures at pages 9 and 10.

Applicant must provide appropriate amendments to the specification or drawings inserting the required sequence identifiers. Sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required. If necessary to correct the deficiency, Applicant must submit paper and computer-readable copies of a substitute sequence listing, together with a statement that the content of both copies are the same and, where applicable, include no new matter.

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8. Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

9. Claims 1, 2, 5, 8-12, 47, 48, and 68 are allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
October 19, 2004

  
LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER

<b>Notice to Comply</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/512,581	SOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
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**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: As noted in the attached Office action, sequences depicted in Figures 2, 3, and 5 are not identified by sequence identification numbers; and it is noted that these sequences do not appear in the instant sequence listing.

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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